FDA and APHIS have been participating in bilateral Mutual Recognition Agreement talks. These talks are being led by the Office of the U.S. Trade Representative and the Department of Commerce and by representatives of the European Union. FDA and APHIS will meet with representatives from the European Union and its Member States from April 3 to April 5, 1995, in Brussels, Belgium to exchange information on their respective programs. During the Brussels meeting, U.S. industry will have the opportunity to present its experience with U.S. and European GMP and quality control programs.

Dated: March 24, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–7740 Filed 3–24–95; 3:14 pm]

BILLING CODE 4160–01–F

Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Drug Evaluation and Research (CDER) has placed on certain investigational new drug trials. The committee was established as a 1-year experiment in August 1991. The committee met quarterly through 1992 and currently meets semiannually as a regular program. The committee last met in October 1994. FDA is inviting any interested drug company to use the confidential mechanism to submit to the committee for its review the name and number of any investigational new drug trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in June 1995. Drug companies may submit review requests for the June meeting before April 27, 1995.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1306.

FOR FURTHER INFORMATION CONTACT: Deborah A. Wolf, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION: FDA regulations at part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational drug. The IND must contain the study protocol, a summary of human and animal experience with the drug, and information about the drug's chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of subjects and to help ensure that the quality of any scientific evaluation of drugs is adequate to permit an evaluation of the drug's efficacy and safety. An investigational new drug for which an IND is in effect is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may impose a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

FDA regulations at 21 CFR 312.42 describe the grounds for the imposition of a clinical hold. When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for the imposition of a hold order, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, the agency may order a clinical hold. In CDER, a clinical hold is ordered by or on behalf of the director of the division that is responsible for review of the IND. The order identifies the studies under the IND to which the hold applies and explains the basis for the action. The hold order may be made by telephone or other means of rapid communication, or in writing. Within 30 days of the imposition of the clinical hold, the division director provides the sponsor with a written explanation of the basis for the hold. Any sponsor who has not received a written explanation within 30 days should notify the division and request that it be issued. In addition to providing a statement of reasons, this ensures that the hold is recorded in CDER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit the resumption, an investigation may resume only after the division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

FDA regulations at 21 CFR 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, a sponsor may request a meeting with the review staff and management to discuss the hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center's practices in imposing clinical holds. First, CDER completed a center-wide review of clinical holds recorded in the management information system. While some differences in practice and procedure were discerned among divisions, it appeared that the procedures specified in the regulations were, in general, being followed, and that holds were scientifically supportable.

Second, FDA established a committee in CDER to review selected clinical holds for scientific and procedural quality. The committee held pilot

meetings in 1991 and 1992. The trial phase of the committee review process confirmed the agency's view that the divisions in CDER impose clinical holds in a matter that is generally consistent with FDA's procedural requirements and that holds are imposed on scientifically supportable grounds.

The clinical hold committee review process is now a regular, ongoing program. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending hold to have that hold considered ''anonymously.'' The committee consists of senior managers in CDER, a senior official from the Center for Biologics Evaluation and Research, and FDA's Chief Mediator and Ombudsman. The committee now meets semiannually. The committee last met in October 1994.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review holds proposed for review by drug sponsors. In general, a drug sponsor should consider requesting review when it disagrees with the agency's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to FDA's Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CDER staff, with the exception of the Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CDER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, will be available from the Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new drug trial that was placed on clinical hold during the past 12 months that they want the committee to review at its June meeting. Submissions should be made by April 27, 1995, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: March 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–7575 Filed 3–27–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda

To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: April 12, 1995.

Time: 2 p.m.

Place: NIH, Westwood Building, Room 303, Telephone Conference.

Contact Person: Dr. Joe Marwah, Scientific Review Administrator, 5333 Westbard Ave., Room 303, Bethesda, MD 20892, (301) 594–7158.

Name of SEP: Biological and Physiological Sciences.

Date: April 18, 1995.

Time: 12:30 p.m.

Place: NIH, Westwood Building, Room 417B, Telephone Conference.

Contact Person: Dr. Gerald Greenhouse, Scientific Review Admin., 5333 Westbard Ave., Room 417B, Bethesda, MD 20892, (301) 594–7385.

Name of SEP: Multidisciplinary Sciences.

Date: April 26, 1995.

Time: 10 a.m.

Place: NIH, Westwood Building, Room 2A15, Telephone Conference.

Contact Person: Dr. Houston Baker, Scientific Review Administrator, 5333 Westbard Ave., Room 2A15, Bethesda, MD 20892, (301) 594–7374.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 83.892, 93.893, National Institutes of Health, HHS)

Dated: March 21, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–7515 Filed 3–27–95; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 59 FR 60997–8, November 29, 1994) is amended to reflect the reorganization of the Office of the Director, National Institute of Allergy and Infectious Diseases (OD/NIAID). The reorganization consists of the following: (1) Retitle the (a) Office of Administrative Management (HNM17) to the Office of Administrative Services (HNM17); (b) Financial Management and Information Systems Branch (HNM173) to the Office of Financial Management (HNMI2); and (c) Personnel Management Branch (HNMI74) to the Office of Human Resources Management (HNM14); (2) establish the Office of Technology Information Systems (HNM15); and (3) transfer the functions of the Office of Tropical Medicine and International Research (OTMIR) (HNM19) to the Division of Microbiology and Infectious Diseases (HNM5) and abolish the OTMIR. This reorganization will enable the NIAID to better fulfill its mission by restructuring the OD/NIAID to better integrate related program areas and streamline operations.

Section HN–B, Organization and Functions is amended as follow: (1) Under the heading *Office of the Director (HNM1), National Institute of Allergy and Infectious Diseases (HNM),* insert the following:

Office of Financial Management (HNM12). (1) Serves as principal advisor to the Institute Director, Deputy Director for Management and Operations, and Division Directors in the financial management aspects of the planning, formulation, execution, and evaluation of the Institute's research grant, training, and intramural research programs; (2) collaborates with program planning staff in the development and coordination of the Institute programs with the budget process; (3) formulates and monitors the Institute's financial management program and establishes a system of effective control of funds utilized